

AMENDED IN SENATE MAY 3, 2006
AMENDED IN SENATE APRIL 20, 2006
AMENDED IN SENATE MARCH 30, 2006

SENATE BILL

No. 1763

Introduced by Senators Figueroa and Kuehl

February 24, 2006

An act to add Division 112.7 (commencing with Section 130675) to the Health and Safety Code, relating to compulsory licensing of pharmaceutical drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1763, as amended, Figueroa. Pharmaceuticals: compulsory licensing.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would, *upon a declaration of a state of emergency*, authorize the Governor to issue a declaration of ~~a state of emergency~~ *necessity* to allow for compulsory licensing of pharmaceuticals if specified conditions are met. The bill would also authorize the department to issue a license for the manufacture of the pharmaceutical drug described in the declaration of ~~a state of emergency~~ *necessity*, and include other related provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 112.7 (commencing with Section 130675) is added to the Health and Safety Code, to read:

DIVISION 112.7. COMPULSORY LICENSING OF
PHARMACEUTICAL DRUGS

130675. For purposes of this division, the following definitions shall apply:

(a) “Department” means the State Department of Health Services.

(b) “Use by the state” means the provision of a pharmaceutical drug subject to the license allowed pursuant to this division to an individual for whom the state provides financial payment or assistance for health benefits, including state employees, beneficiaries of Medical, beneficiaries of Medi-Cal, and other state pharmacy programs, individuals under the supervision of the Department of Corrections and Rehabilitation, free health clinics, and beneficiaries of workers’ compensation.

130676. (a) ~~The Governor may declare a state of emergency~~
Upon a declaration of a state of emergency, the Governor may issue a declaration of necessity to allow for compulsory licensing pursuant to this division to address a public health need.

(b) ~~The declaration of a state of emergency~~ *necessity* to allow for compulsory licensing shall include all of the following:

(1) The public health and safety emergency for which issuing the license to manufacture is necessary.

(2) A list of the relevant patents, exclusive marketing periods, copyrights, trademarks, and any other relevant property to be licensed under this division.

(3) The proposed license, including proposed compensation rate.

(c) The department shall establish a process to notify the public of the declaration of necessity and to disseminate information to pharmacists, local public health officers, and any other individuals or groups, as deemed necessary by the department.

(d) The notice of the declaration of ~~a state of emergency~~
necessity to allow for compulsory licensing and a copy thereof

1 shall be sent to the registered agent in the state of incorporation
2 of each company that may be affected by the licensing.

3 (e) The licensure process shall be conducted by the department
4 and shall ensure due process to any company affected by the
5 license.

6 ~~130676.~~

7 130677. (a) The department shall establish a process to
8 permit any person affected by the compulsory licensing may
9 appeal the licensure of the property listed in the declaration.

10 (b) If no notice of intervention is filed, the department may
11 issue the license pursuant to Section 130677.

12 ~~130677.~~

13 130678. (a) If the requirements of Sections ~~130675 and~~
14 ~~130676 130676 and 130677~~ are met, the department may issue a
15 license for the manufacture of the pharmaceutical drug described
16 in the declaration of ~~a state of emergency~~ *necessity* to allow for
17 compulsory licensing. In addition the department shall notify the
18 owner of the property being licensed of the amount of just
19 compensation and any terms or conditions contained in the
20 opinion of the department after the expiration of the appeal
21 period.

22 (b) The department may assign the license to one or more
23 manufacturers of pharmaceutical drugs solely for the
24 manufacture of the pharmaceutical drug for the use by the state
25 and other states that have issued substantially similar licenses.

26 130678. Nothing in this division shall operate as a waiver of
27 the state's sovereign immunity.